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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,059	02/05/2002	Lee A. Mizzen	12071-017002	8333

26161 7590 06/20/2003

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225 FRANKLIN ST  
BOSTON, MA 02110

EXAMINER
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MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/20/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/068,059

Applicant(s)

Mizzen et al

Examiner

Mosher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/4/2002, 7/25/2002, 11/29/2002, 12/30/2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7, 9 6) ☐ Other:

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claims 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 11 are indefinite in referring to a figure instead of a SEQ ID number. This affects the dependent claims.

### ***Claim Objections***

Claims 12-15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim, and because a multiple dependent claim may refer to claims in the alternative only. See MPEP § 608.01(n). In the interest of compact prosecution, parent claim 10 has been treated as if it depended from claim 1, and claim 15 has been treated as if it depended only from claims 1 to 7.

Claims 4 and 5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 4 and 5 require a fragment of the HB. core antigen, but depend from a claim requiring a core antigen. Since a fragment of a protein is not a further limitation of a protein (any more than benzene is a further limitation of naphthalene), these claims are outside the scope of the parent claim..

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8-10, 12, 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young 6,338,952 in view of Tabor et al 4,547,368. Young teaches broadly that fusion of a stress protein to an antigen induces or enhances an immune response against the antigen. Young teaches a viral antigen as appropriate, see for example claim 6, 24, 43, 51, 75. This differs from the claimed invention in that Young does not specifically teach hepatitis B virus core antigen. However, Tabor teaches HBV core antigen as a desirable immunogen. Therefore it would have been obvious to choose this species of virus antigen for use as broadly taught by Young, with reasonable expectation of success.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Tabor et al as applied to claims 1-4, 8-10, 12, 14-18 above, and further in view of Birkett 6,231,864. These claims differ from the above in that they require removal of all or a part of the C-terminal arginine-rich domain of HBV core antigen. Birkett teaches that this region is undesirable because it binds DNA, see for example column 10, lines 51-57, and col. 13, lines 9-15. Therefore

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it would have been obvious to remove this region to avoid this complication, with reasonable expectation of success.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Tabor et al as applied to claims 1-4, 8-10, 12, 14-18 above, and further in view of Mizzen et al WO 98/23735. These claims differ from the above by requiring administration of a nucleic acid encoding the fusion protein. Mizzen teaches that the nucleic acid is an alternative to the protein for in vivo administration of a stress protein/antigen fusion, see for example page 29 line 7 through page 30, line 18. Therefore it would have been obvious to use this alternative immunization method, with reasonable expectation of success.

Claims 10, 12-15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of either Thoma 6,020,167 or Jolly et al 6,297,048 in combination with the teachings of Young 6,338,952. Both Thoma and Jolly teach a retroviral vector expressing HBV core antigen, and its therapeutic use. This differs from the invention in that neither reference teaches fusion of the antigen to a stress protein. However, Young teaches improved immune response to any antigen fused to a stress protein, and improved immune response is always desirable. It would have been within the ordinary skill of the art to modify Thoma or Jolly by fusing a stress protein (or portion thereof) to the HBV core antigen sequence, for the purpose of improving the immune response, with reasonable expectation of success.

Sequence ID numbers 5-12 are seen as free of the art, because the HBV core sequence in these fusion products contains at least an Isoleucine -> Phenylalanine substitution compared to the

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closest prior art sequence, and the prior art does not appear to provide motivation to modify this specific residue when fusing an HBV core sequence to a stress protein sequence. See for example the attached alignment, showing a typical "best match" for the HBV moiety of SEQ ID NO:10.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone numbers for this Group are now (703) 872-9306 for Before Final responses, and (703) 872-9307 for After Final responses. Faxes for this Group can also be sent to (708) 308-4242..

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 19, 2003

*Mary Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800/600